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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/988,850

11/19/2001

John F. Gordon

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7587

23483

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05/21/2004

HALE AND DORR, LLP  
60 STATE STREET  
BOSTON, MA 02109

EXAMINER

YANG, NELSON C

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/988,850

Applicant(s)

GORDON ET AL.

Examiner

Nelson Yang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 03/26/04
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendment of claim 7 and addition of claims 8-28 are acknowledged and have been entered.

### ***Rejections Withdrawn***

2. Applicant's arguments, see p.10, filed March 26, 2004, with respect to the priority have been fully considered and are persuasive. The objection to the priority has been withdrawn.
3. Applicant's arguments, see p.11, with respect to the objection of the abstract have been fully considered and are persuasive. The objection of the abstract has been withdrawn.
4. Applicant's arguments, see p.11, with respect to the rejections of claim 7 under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejection of claim 7 under 35 U.S.C. 112, second paragraph, has been withdrawn.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "semi-reflective" in claim 19 is a relative term which renders the claim indefinite. The term "semi-reflective" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would

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not be reasonably apprised of the scope of the invention. Specifically, it is unclear how much reflectivity would render the information layer to be considered semi-reflective as opposed to reflective or unreflective.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Coleman [US 3,799,742].

With respect to claim 20, Coleman teaches an analyte test container comprising a separation chamber (reception chamber) with an inlet formed when a closure is pushed down to rupture membrane 302 and, a filter means in fluid connection with the separation chamber (fine mesh filter), multiple mixing chambers (reaction chambers) in direct fluid communication with the separation chamber and not in direct fluid communication with each other, and multiple detection chambers (cuvettes) (figs. 22, 29, 35, col. 14, lines 21-57, col.15, line 15-36, col.21, lines 15-49).

9. With respect to claim 21, Coleman teaches the presence of inlet ports connected to the mixing chamber (fig. 22 (318, 322, and between 312 and 314, 316), fig. 29 (530, 560), fig. 35 (770, 772, 790, 800), col. 14, lines 21-57, col. 15, line 15-36, col.21, lines 15-49).

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10. With respect to claim 22, Coleman teaches that the cover portion cooperates with the tray portion to provide closed chambers within the container body (col.5, lines 20-25). Joinder may be effective by a suitable adhesive or by cohesive bonding.

11. With respect to claims 24-26, Coleman teaches that the cover portion cooperates with the tray portion to provide closed chambers within the container body (col.5, lines 20-25). Joinder may be effective by a suitable adhesive or by cohesive bonding.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 7-13, 23-26, rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman [US 3,799,742] in view of Sheppard, Jr. et al [US 6,319,468].

With respect to claims 7, 23, Coleman teaches an analyte test container comprising a separation chamber (reception chamber) with an inlet formed when a closure is pushed down to rupture membrane 302 and, a filter means in fluid connection with the separation chamber (fine mesh filter), multiple mixing chambers (reaction chambers) in direct fluid communication with the separation chamber and not in direct fluid communication with each other, and multiple detection chambers (cuvettes) (figs. 22, 29, 35, col. 14, lines 21-57, col.15, line 15-36, col.21, lines 15-49). While Coleman teaches the use of dry reagents in the detection chambers, Coleman does not specifically teach the use of capture zone within the detection chambers.

Sheppard, Jr. et al, however, teach that a surface or detection chamber treated to comprise a specific binding reagent allows for the detection of a particulate, such as a cell expressing a cognate antigen, receptor or adhesion protein (col. 10, lines 32-45). Therefore it would have been obvious in the invention of Coleman to have a capture zone, as suggested by Sheppard, Jr. et al, in order to allow for the detection of a particulate, such as a cell expressing a cognate antigen, receptor or adhesion protein.

14. With respect to claims 8, 9, Coleman teaches the presence of inlet ports connected to the mixing chamber (fig. 22 (318, 322, and between 312 and 314, 316), fig. 29 (530, 560), fig. 35 (770, 772, 790, 800), col. 14, lines 21-57, col. 15, line 15-36, col.21, lines 15-49).

15. With respect to claims 10-13, Coleman teaches that the cover portion cooperates with the tray portion to provide closed chambers within the container body (col.5, lines 20-25). Joinder may be effective by a suitable adhesive or by cohesive bonding.

16. Claims 14-15, 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman [US 3,799,742] and Sheppard, Jr. et al [US 6,319,468], as applied to claims 7, 20 above, and further in view of Chow [US 6,167,910].

Coleman teaches the use of a cap and substrate, as discussed above. Coleman does not teach the use of a channel layer, with separation, mixing, and detection chambers formed in the channel layers.

Chow, however, does teach the use of multi-layered channels and chambers. Chow further teaches that providing multi-layered channel structures and networks and taking advantage of both surfaces of planar substrates, optimal use of substrate materials is permitted, allowing further miniaturization of fluidic processes and providing cost advantages in terms of

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substrate conservation (col.3, lines 10-26). Therefore it would have been obvious in the device of Coleman and Sheppard, Jr. et al to have a channel layer, with separation, mixing, and detection chambers formed in the channel layer, as suggested by Chow, in order to allow further miniaturization of fluidic processes and providing cost advantages in terms of substrate conservation.

17. Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman [US 3,799,742], as applied to claims 7, 20 above, and further in view of Chow [US 6,167,910].

Coleman teaches the use of a cap and substrate, as discussed above. Coleman does not teach the use of a channel layer, with separation, mixing, and detection chambers formed in the channel layers.

Chow, however, does teach the use of multi-layered channels and chambers. Chow further teaches that providing multi-layered channel structures and networks and taking advantage of both surfaces of planar substrates, optimal use of substrate materials is permitted, allowing further miniaturization of fluidic processes and providing cost advantages in terms of substrate conservation (col.3, lines 10-26). Therefore it would have been obvious in the device of Coleman et al to have a channel layer, with separation, mixing, and detection chambers formed in the channel layer, as suggested by Chow, in order to allow further miniaturization of fluidic processes and providing cost advantages in terms of substrate conservation.

18. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman [US 3,799,742] and Sheppard, Jr. et al [US 6,319,468], as applied to claim 7 above, and further in view of Mian et al [US 2001/0055812].

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Coleman and Sheppard, Jr. et al teach the use of analyte test containers, as discussed above, but fail to teach the use of an information layer configured to retain encoded information.

Mian et al, however, teach the use of an information layer comprised of a planar surface encoded with an instruction set for controlling rotational speed, duration or direction (claim 1), facilitating operation of the microsystem assays (paragraph 0222-224). Therefore it would have been obvious in the device of Coleman and Sheppard, Jr. et al to have an information layer comprised of a planar surface encoded with an instruction set for controlling rotational speed, duration or direction, as suggested by Mian et al, in order to facilitating operation of the microsystem assays.

### ***Response to Arguments***

19. Applicant's arguments with respect to claim 7 have been considered but are moot in view of the new ground(s) of rejection. However, the following arguments are addressed in order to further expedite the prosecution.

20. In response to applicant's argument that the prior art had not disclosed mixing and detection chambers on p. 12, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Therefore, if applicant can show why the prior art structures were not capable of performing the



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intended uses recited in the instant claims, or demonstrate why the prior art structures would be different from the structures recited in the instant claims, it would be greatly appreciated.

### *Conclusion*

21. No claims are allowed.

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

23. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang  
Patent Examiner  
Art Unit 1641



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05/15/04